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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,545	08/21/2003	Douglas S. Hine	P-11138.00	9714

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EXAMINER

ALTER, ALYSSA M

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,545

Applicant(s)

HINE ET AL.

Examiner

Alyssa M. Alter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/15/04 & 2/02/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the limitation "of the array of lead contact elements" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, 6-8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Pohndorf et al. (US 4,628,934). Pohndorf et al. discloses a pacemaker with a connector bore for electrically and mechanically connecting the implantable medical device (IMD) with two adaptors and multi-electrode leads as displayed in figures 6 and 7. The array of lead connector elements are displayed in figure 2 as "sleeves 151 and 152 (in contact with rings 141 and 142) (col. 7, lines 63-64)". The sleeves are connected to electrodes, with a conductor for each electrode. The two adaptors, which the examiner considers to be a plurality of adaptors, have an inner

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lumen for engaging the sleeves of the lead with rings to create an electrical and mechanical connection. In addition, the adaptors have an external surface used for engagement with the electrical bore. This engagement surface has two contact zones, the pin as the first zone and sleeves of the lead as the second zone, which connects within the IMD with the socket and rings, respectively.

Since the lead connectors are located circumferentially around the lead, the examiner considers the connectors to be connector rings. In addition, a connector ring is located adjacent to the sealing ring and distal to the remainder of the array of lead connectors. Therefore, since the ring conductor makes contact with the bore of the IMD by means of the adaptor, the connector ring is located distal to the array of lead connector elements and electrically connected to the IMD bore.

Within the adaptor-lead connector, there are two sealing rings. One sealing ring, as previously mentioned, is located distal to the array of connector elements located on the lead. The other sealing ring is located on the adaptor located proximal to the array of connector elements.

Outer surface of a male connector piece closely matched the inner surface of a female connector piece the connection assembly is dimensioned to be press fit. Therefore, since the sleeves or array of lead connector elements on the cylindrical male piece closely match the rings or contact elements located within the adaptor on a cylindrical female piece, the connection assembly is press fit.

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Although, Pohndorf et al. is silent about the adaptors conforming to industry standard, it is inherent that the adaptors do conform to an industry standard in order for them to adequately perform with an IMD.

As to claims 1, 3 and 7, It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being obvious over Pohndorf et al. (US 4,628,934) in view of Peers-Trevarton (US 4,469,104). Holleman et al. discloses the claimed invention except for the protrusions for each contact element within the array of lead contact elements. Peers-Trevarton teaches that it is known to utilize protrusions and depressions to mechanically and electrically engage the lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical connections of the lead as taught by Pohndorf et al. with the electrical and mechanical connections as taught by Peers-Trevarton since such

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a modification would be a substitution of f known functional equivalents by substituting electrical connectors to electrically engage the lead.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Bischoff et al. (US 5,843,141) discloses a medical lead connector system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M. Alter

Alyssa M Alter
Examiner
Art Unit 3762


JEFFREY R. JASTRZAB
PRIMARY EXAMINER

5/31/05